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**GREGG INCLUDES MEASURE TO MAKE MORE PRESCRIPTION
DRUGS AVAILABLE IN MEDICARE REFORM BILL**

Sen. Gregg amendment approved by full Senate, added to Medicare bill currently being debated in U.S. Senate

WASHINGTON— The U.S. Senate today voted to include a measure, introduced by Senator Judd Gregg (R-NH), Chairman of the Senate Health, Education, Labor and Pensions Committee, that will make more affordable prescription drugs available to more people. The amendment passed by a vote of 94 to 1; the Medicare bill is still pending before the Senate.

"This amendment represents a victory for every person in America who has ever used a prescription drug to enhance or prolong their life and good health. The Greater Access to Affordable Pharmaceuticals amendment would eliminate the various practices some brand-name pharmaceutical and generic companies have used to delay consumers access to low-cost affordable medicines. It also does it in a way that protects innovation and preserves the incentive for companies to invest in the research & development of the next generation of newer, better, and safer drugs." said Senator Judd Gregg.

The agreement that enabled the generic legislation to be marked up in the HELP Committee last week and reach the Senate floor today was achieved by Senators Judd Gregg, Charles Schumer (D-NY), John McCain (R-AZ) and HELP Ranking Member Ted Kennedy (D-MA). It will enable less expensive generic drugs to be sold in pharmacies. The Gregg-Schumer proposal overhauls provisions of Hatch-Waxman (drug patent laws) that have created a significant stifling of the system with frivolous law suits, which delay life-saving drugs from reaching consumers in efficient and less expensive means. The plan also strengthens a Food and Drug Administration proposal from last fall that was intended to pave the way for generics to come to the market faster and shield that proposal from legal challenges.

A bill summary sheet is attached.

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Bill Summary:

Current US drug patent laws (known as Hatch-Waxman) were designed to strike a balance between rewarding blockbuster drug companies for their research and development while ensuring that less expensive generic drugs are available to consumers. But in the years since these laws were enacted, the namebrand industry has stifled low-cost competition with a host of tactics - including filing frivolous patents with the FDA on the color of a pill bottle and paying generic manufacturers not to sell their drugs. In so doing, these tactics allow the namebrand companies to keep charging exorbitant prices and delay the arrival of lower-cost alternatives.

These tactics have caused drug prices to soar and forced the gap between the cost of brand name drugs and their generic alternatives to skyrocket in the last decade. In 1990, the average cost per prescription for brand-name medications was \$27.16, while the average cost for generic drugs was \$10.29. By 2000, the average cost per prescription reached \$65.29, while the generic increased to only \$19.33. Last summer, the Senate passed legislation sponsored by Schumer and McCain that significantly overhauled Hatch-Waxman. For the individual, that legislation would have meant hundreds of dollars in savings on drug costs per year.

The Gregg-Schumer proposal would achieve comparable savings to the original Schumer-McCain measure but uses a different approach to modify the patent laws. In so doing, it addresses a number of the criticisms made against Schumer-McCain. As a result, the lawmakers expect that the bill should be able to garner even more support and stands a very good chance of being enacted. The Senate HELP Committee's action heads to full Senate now for approval. The key elements of the Gregg-Schumer proposal are as follows:

1) **One 30 Month Stay** - The name-brand company would get a single 30 month stay. The stay would be triggered if a name-brand company sues a generic application for infringing on any patent on a blockbuster drug that is filed before a generic application is submitted to the FDA.

Once a generic application is filed, the name-brand company has 45 days to challenge the generic application in court. If the name-brand does not challenge the generic company's application within 45 days, the generic can seek a declaratory judgement indicating that it does not violate the name-brand drug's patents.

The single 30 month stay would run concurrent to the FDA's consideration of the generic company's application. As such, the 30 month stay would not be likely to cause significant delay in the generic's introduction to the marketplace. (It usually takes the FDA 18 to 25 months to approve a generic drug.) In contrast, the FDA's proposed rule would allow the stay to be triggered up to the eve of the generic drug coming to market.

2) **Enforcement** - The Gregg-Schumer plan does not specify which patents can be listed in the FDA's Orange Book. To ensure that the name-brand companies do not use frivolous patents to keep generic drugs off the market, the proposal would create a new enforcement mechanism.

Gregg-Schumer would allow generic companies to file counter-claims if a name-brand company sues

them for violating a patent. For example, if a name-brand files a frivolous patent and sues a generic applicant for violating that patent in order to trigger the 30 month stay, the generic company can counter-sue the name-brand and argue that the patent should never have been listed in the Orange Book in the first place.

3) Forfeiture of 180 Day Exclusivity - Currently, the first generic drug company who is able to come to market gets 180 days of exclusivity. Gregg-Schumer sets up "forfeiture provisions" similar to those in earlier generic drug legislation which prevent the generic companies from abusing this incentive.

The first-to-file an ANDA would forfeit the 180-day exclusivity period if the applicant fails to market the drug within 75 days after the ANDA is approved. Additionally, in the event another applicant has obtained a favorable, final, and unappealable court decision on the patents that created the first applicant's 180-day exclusivity, the first applicant must go to market within 75 days or forfeit the exclusivity.

A first applicant would also forfeit its 180-day exclusivity if it withdraws its ANDA; amends or withdraws its certifications on the patents that created the exclusivity; fails to get tentative approval of its ANDA within 30 months; enters into an agreement with the brand-name company or another generic company that the Federal Trade Commission (FTC) or a court determines is anti-competitive, or; if all patents that created the exclusivity expire.

If a first applicant forfeits its exclusivity, any other applicant may come to market immediately, without first having to wait 180 days. The forfeiture events in this Act prevent the 180-day exclusivity from acting as a bottleneck to generic competition. Combined, the exclusivity incentive and these forfeiture events encourage both first and subsequent applicants to vigorously seek approval of their applications.

4) Bioequivalence - Under the current statute, the primary method by which the FDA determines whether a generic is equivalent to a brand drug ("bioequivalence") is by measuring the rate and absorption of the drug into the bloodstream. For certain drugs which are not absorbed into the bloodstream, such as topicals and inhalers, the FDA uses different tests to determine bioequivalence, which are defined in their regulations. Brand companies have challenged FDA's use of these regulations, which has led to delay in the approval of generic versions of these drugs.

Gregg-Schumer would clarify that the FDA does have the authority to establish separate tests for determining the bioequivalence of drugs which are not absorbed into the bloodstream - as long as those tests are scientifically valid and meet rigorous standards.

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